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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,972	12/01/2003	Lynn Doucette-Stamm	PATH03-16	3315

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,972	DOUCETTE-STAMM ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1- 32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 32 drawn to DNA, classified in class 536, subclass 23.7.

Further restriction to one SEQ.ID.NO required (see paragraph # 2).

II. Claims 14-16, drawn to methods of treatment comprising administering DNA molecules, classified in class 514, subclass 44.

Further restriction to one SEQ.ID.NO required (see paragraph # 2).

III. Claims 17-20, drawn to polypeptides, classified in class 530, subclass 350.

Further restriction to one SEQ.ID.NO required (see paragraph # 2).

IV. Claims 21-23, drawn to methods of treatment comprising administering polypeptide, classified in class 424, subclass 184.1

Further restriction to one SEQ.ID.NO required (see paragraph # 2).

V. Claim 24 drawn to methods of detecting Streptococcus, classified in class 435, subclass 6.

Further restriction to one SEQ.ID.NO required (see paragraph # 2).

VI. Claims 25-27 or 28-29 or 30-31 drawn to computer medium, computer based system or a method for identifying nucleic acid using database system or a method for identifying an expression modulating factor using database system, classified in class 702, subclass 20.

Further restriction to one SEQ.ID.NO required (see paragraph # 2).

2. Additionally, Groups I-VI are further restricted according to MPEP 803.04 which sets forth that molecules with a distinct sequence are distinct inventions. Accordingly, applicant is restricted to a single sequence for examination (e.g., SEQ ID NO:3773, 3774, etc). Therefore, election is required of one of inventions I – VI and one of SEQ ID NO.

Inventions SEQ ID NO: 1-3772 or 3773-7544 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions; represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct since each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO. Restriction is deemed proper because these products appear to constitute patentably distinct inventions. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO from any group elected.

3. The inventions are distinct, each from the other because of the following reasons: invention 1, drawn to DNA and invention III drawn to a protein molecule are distinct since they are products with a different structure and biological properties. The protein is made of amino acids whereas the nucleic acid molecule consists of nucleotides. Further methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making the nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ï 806.05(h)). In the instant case the method of treatment can be readily practiced with well-known antibiotics, e.g. tetracycline.

5. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ï 806.05(h)). In the instant case the method of treatment can be readily practiced with well-known antibiotics, e.g. tetracycline.

6. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP j 806.05(h)). In the instant case the detection of Streptococcus in a sample can be accomplished via affinity chromatography.

7. Invention VI is distinct from Inventions I-V since it requires a computer-based medium. Further, the medium containing nucleotides not only used for storing the recorded data but also can be used in different methods such as a method for identifying nucleic acid using database system or a method for identifying an expression-modulating factor etc. Therefore, if applicants elect group VI, then applicant is required to elect either computer medium or one method.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is

proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1 .143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1 .48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1 .48(b) and by the fee required under 37 CFR 1 .17(i).

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

L. F. Smith

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